DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 5 2012

Re: ARIDOL
Docket No. FDA-2012-E-0168

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is concerning the application for patent term extension for U.S. Patent No. 5,817,028 filed by Pharmaxis Ltd., under 35 U.S.C. 156. The human drug product claimed by the patent is ARIDOL (mannitol), which was assigned new drug application (NDA) No. 22-368.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). However, our records also indicate that ARIDOL does not represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1).

The active ingredient in ARIDOL has been previously approved for commercial marketing or use in many new drug applications, including APP Pharmaceutical's Mannitol injection, B. Braun's Mannitol injection, Baxter Healthcare's Osmitrol injection, B. Braun's Resectisol irrigation solution, Hospira's Mannitol injection, and others.

NDA 22-368 was approved on October 5, 2010, which makes the submission of the patent term extension application on December 3, 2010, timely within the meaning of 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Rudy J. Ng
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